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Research Update

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The Home INR Study (THINRS)

Can patient self-testing for prothrombin time by international normalized ratio (INR) decrease major health outcomes such as stroke, major bleeding, or death, compared to conventional anticoagulation service care? That's what David Matchar, MD, of the Durham VA Medical Center, Alan Jacobson, MD, of the Loma Linda VA Medical Center, and Robert Edson, MA, of the Palo Alto Cooperative Studies Program Coordinating Center would like to determine with a Cooperative Studies Program funded \$12 million grant that began April 2002 and runs through December 2006.

"This is a large randomized trial of two different approaches to managing patients on chronic anticoagulation," says Dr. Matchar. "The Home INR Study (THINRS) will make use of new technology that has, in the last few years, been approved for patients to monitor their warfarin anticoagulation at home. It has been proposed that more frequent testing and greater patient involvement can help improve the quality of use of warfarin. Warfarin can be difficult to manage. New medications or changed doses, concurrent illness, dietary changes can raise or lower INR, leading to risk of bleeding or thromboembolism. With this technology, patients can monitor themselves both more frequently and on an ad hoc basis, if there is a change in their health, diet, or medication. This will allow patients and their doctors a flexibility they have never had before."

There are 29 VA Medical Centers participating in THINRS, with a target of 3,200 patients. The study has two phases. In the first phase, consenting candidates for self-testing will be evaluated for their ability to use the anticoagulation home monitoring devices. In the second phase, those candidates found capable of self-testing will be randomized, with consent, to weekly self-testing or to usual care

in an anticoagulation service.

The primary outcome measure will be defined by the percent of patients who have a stroke, major bleed, or die. The secondary outcome measures will be total spent in target INR range, other events such as myocardial infarction, non-stroke thromboembolism or minor bleeds, competence and compliance with the home self-testing device, patient overall satisfaction, patient's ability to make dosing decisions, and associated quality of life.

For patients who will be doing the home self-monitoring, the VA has developed a telephone-based response system so they can dial in at a certain interval to provide information about who they are, what their INR value is, and if they are having difficulties. "If they call in with problems, or if they fail to call in as scheduled," says Dr. Matchar, "someone at the VA clinic will contact them. This provides a safety net."

"Patient self-testing monitoring device can be a very empowering technology," says Dr. Matchar. "Patients are the key to the whole process. They develop an awareness that might not otherwise be possible, learning how their body responds to illness, diet, dosing changes, and so on."

"Patient self-monitoring has an advantage for the anticoagulation clinic as well. Seeing a patient once a month, the provider might be reluctant to make a change with the patient's medication – say when the patients INR is a bit low – because it's difficult to get the patient back in the appropriate time window of five to seven days," says Dr. Matchar. "Patient self-testing may improve the common problem of underanticoagulating 'just a bit' which can lead to loss of treatment effectiveness. Availability of home testing could increase the providers level of comfort that the patient will be well managed even when they are not immediately in front of you."

James Tulsky to Begin SCOPE Study

When cancer patients are faced with the transition from fighting a potentially curable disease to recognizing that conventional medical treatment will no longer be effective, accepting palliative or hospice care challenges their physical, emotional and spiritual integrity, and leaves them emotionally vulnerable.

Unfortunately, a cancer patient's oncologist may not be prepared to be equipped to meet, or aware of the patient's needs. They may see stopping no longer effective cancer treatments as a failure, or experience sadness at the anticipated loss of their patient, or may simply lack the communication skills to convey empathy and respond to the patients' emotions. Recent studies indicate that many physicians miss cues or ignore limited opportunities to address a patient's emotional concerns, in part to not wanting to decrease a patient's sense of hopefulness towards their prognosis.

Researchers James Tulsky, M.D., Kathryn Pollak, Ph.D., Robert Arnold, MD, Celette Skinner, PhD, Maren Olsen, PhD, David Farrell, MPH, Amy Abernethy, MD, Keith Meador, MD, ThM, MPH, and Terrance Albrecht, PhD, however, would like to change the communication patterns between oncologist and their patients, allowing for greater communication and to better meet the needs of the terminal patient's emotional and spiritual distress as well as their immediate and long-term medical concerns. "The overall goal of this project is to expand the field of oncologist-patient communication," says Dr. Tulsky, lead investigator of the study, "by enhancing our understanding of how oncologists and patients communicate about the transition to end-of-life care, identifying key communication skills that may assist patients through difficult transitions, and creating and testing an easily disseminable intervention to help physicians implement these skills."

The study, titled Studying Communication in Oncologist Patient Encounters (SCOPE), will record oncologists and their patients as they discuss the transition from active cancer treatment to palliative care. These conversations will then be compared with best practices described in the literature with attention being placed on communication behaviors "that promote patient disclosure of concerns, use of emotion handling skills, recognition of empathic opportunities, and the conveying of prognostic information." Based on these recorded conversations an interactive CD-ROM will be developed to improve the oncologist's communication skills. The study will then assess this intervention's feasibility by measuring "its effectiveness for changing physician communication behaviors and relevant patient outcomes, including reduced stress and increased satisfaction."

"Our goal is to better equip the dying patient's physician/oncologist at helping the patient make the transition from seeing their cancer as potentially curable to recognizing that medical treatment will no longer be effective," says Dr. Tulsky. "When someone has cancer, they have at every stage little losses. At first it may be functional losses and the patient is able to do less and less along the way. They may lose sense of personality,

their beauty, their sexuality, any number of things keep being taken away. Patients may feel overwhelmed as they struggle with issues related to loss of control, the meaning of their illness, uncertainty regarding the dying process, and unfulfilled goals. I think that's where the transition is. The patient's hope has all been centered on cure, or long-term remission. The transition goes toward good function and quality of life while a short time is left, and towards other kinds of goals, whether they be spiritual goals or some sort of legacy for family and loved ones. Studies have shown that quality of communication affects psychological well-being of cancer patients, with patient-centered consultations leading to improved satisfaction and psychological adjustment. The physician's challenge is to help a patient through this transition in a way that helps preserve or enhances their relationship with the patient, and not increase the emotional suffering the patient is going through.

The SCOPE study has a grant of \$2,095,000 from the National Cancer Institute and runs from May 2003 through April 2008.

Smoking Cessation Study Begins

The causal link between cigarette smoking and lung cancer is widely acknowledged, yet 25% of American adults continue to smoke, contributing to 90% of the 164,000 people that will be diagnosed with lung cancer this year. Eighty-six percent of this group will die within five years of diagnosis. Though individuals who smoke may be aware of the health effects of smoking, these effects are often viewed as distant or hypothetical events.

For many smokers who have a family member diagnosed with lung cancer, high levels of stress and related coping difficulties may undermine any efforts or resolve to stop smoking. Lori Bastian, MD, the lead investigator, and Mike Kelley, MD, of the Durham VA Medical Center and Duke University, Frank Keefe, PhD, Jennifer Garst MD, Brecedis Peterson, PhD, and Laura Fish MPH, all of Duke University, and Anrea Biddle, PhD, of UNC-Chapel Hill, however, in a study titled "Family Ties," would like to change that. The study, with a grant of \$3,429,000 from the National Cancer Institute, began in June 2003 and runs through June 2008.

"Our goal," says Dr. Bastian, "is to evaluate a stress and coping focused smoking cessation intervention timed to follow a loved one's diagnosis of lung cancer that could be effective for encouraging family members who smoke to consider quitting."

Dr. Bastian and her research team believe that an individuals' diagnosis of terminal lung cancer may be a critical window of opportunity when their relatives or loved one who smoke are in need of and may be particularly receptive to smoking cessation interventions. "In a pilot study led by Dr. Colleen McBride, relatives reported stress related to their loved one's diagnosis of lung cancer, and 79% of this group reported that the patient's diagnosis increased their desire to

quit,” says Dr. Bastian. “Despite this desire to quit, 71% of relatives in this pilot study continued to smoke. Unfortunately, relatives of lung cancer patients may be under greater amounts of stress and depression, two factors that are shown to undermine efforts at smoking cessation.”

Patients will be recruited from three sites: University of North Carolina Hospitals, Duke University Medical Center and the Durham VA Medical Center. Lung cancer patients will be asked to provide contact information on their family members who smoke. The study will then randomly assign 480 relatives that smoke into two groups. One group will receive a letter from the patient’s oncologist encouraging them to quit smoking, a booklet and self-help smoking cessation kit. The second group will also receive a letter from the patient’s oncologist, a booklet and self-help smoking cessation kit and six coping-focused telephone-counseling calls. The researchers hope to show that abstinence from smoking will be higher among those relatives who receive the coping-focused intervention as well as report greater increased coping with stress and greater ease in the ability to quit smoking.

“We hope that by offering an intervention of formalized assistance in taking steps towards quitting smoking and providing an outlet for these people to discuss their fears and concerns about smoking,” says Dr. Bastian, “will be the steps needed for these persons to achieve healthier smoke-free lives.”

Evaluation of Cognitive Impairment in Primary Care Veterans

The Veteran’s Health Administration is the nation’s largest provider of geriatric care, and according to a 1995 survey, 40% of VA outpatient clinic visits were for veterans 65 and older. Age is the strongest risk factor for dementia, which affects between 2-4 million Americans, and those over 65 years-of-age are expected to rise to 20% of the U.S. population by the year 2030. Dementia causes significant suffering for patients through the loss of independence, emotional distress, behavioral symptoms, cognitive decline and safety risks. The cost of caring for dementia is estimated to be \$100 billion per year. It also exacts an emotional toll on the patient’s family and caregivers as well. Fortunately, clinical trials have shown that early diagnosis and medical intervention can reduce the progression of mild cognitive impairment towards greater dementia. Though dementia can be so catastrophic to patients, their families and caregivers and society as a whole, and early detection and intervention can reduce greater onset, early detection for dementia in primary care patients is low. Studies have reported rates of overlooked dementia in 35-90% of cases.

Durham VA researchers Jane DeVeau, M.D., Tracey Holsinger, M.D., John Williams, M.D., Heidi White, M.D., and Cynthia Coffman, Ph.D., however, are working to determine which tests for cognitive impairment can be quick and effective in early detection of dementia in primary care

veterans. The title of the study is “Cognitive Impairment in Primary Care Veterans: An Evaluation of Screening Instruments and Current Quality Care.”

“The study is primarily looking at three different screening instruments for dementia or cognitive impairment in a primary care setting for veterans,” says Dr. DeVeau. “Our first objective is to see how well these three instruments work for detecting dementia or cognitive impairment. The second objective is to see how primary care doctors are diagnosing dementia or cognitive impairment and if they’re documenting that in the patient’s medical record. The third objective is to follow over time what happens when someone does get a diagnosis of dementia – what interventions are made, what tests are ordered, and what kind of diagnostic workup is done.”

The Mini-Mental Status Examination (MMSE); the Mini-Cog (MC); a six-item subset of the MMSE; and a newly created two-item yes/no screener the researchers created are the screening instruments that will be tested – all chosen for their reliability, efficiency and brevity.

The study will occur in the primary and acute care clinics of the Durham VA Medical Center, which is staffed by thirty-seven primary care providers that provide care for 12,759 patients, of which approximately 50% are fifty or older, though only primary care veteran patients 65 or older will be eligible to participate.

“One of the goals of this study is to help ease the eventual burden dementia can have on the individual as well as family members,” says Dr. DeVeau. “We believe that early diagnosis affords patients and their families the ability to learn more about the diagnosis, and plan either financially or legally to anticipate these concerns and to be better prepared for the progression of the disease itself.”

“There is still a big question as to what are the risks and benefits of screening for dementia,” says Dr. DeVeau. “There is not yet a lot of evidence to support screening or not. Our hope is to identify a screening instrument that works better than others in order to be able to make a more reliable diagnosis for our veterans.”

The study is funded by the Hartford Foundation for \$59,400 and runs from March 2003 through February 2005.

Hepatitis C, Gender Differences and Risks Among the Severely Mentally Ill

There is a nationwide hepatitis C infection rate of 2.5 percent among men and a 1.2 percent infection rate among women. But for persons with severe mental illness, hepatitis C rates are much higher and also differ by gender, according to a study conducted by Durham VA researchers and published in the June 2003 issue of *Psychiatric Services*.

The four site study, part of a larger National Institute of Mental Health multi-site study which began more than five years ago, set out to answer three questions concerning hepatitis C infection rates among persons with severe mental illness: 1) Does the prevalence of hepatitis C risk behaviors differ by

gender? 2) Does gender influence the risk of hepatitis C associated with a given behavior? 3) Do gender differences in hepatitis C risk behaviors account for the differences in hepatitis C infection rates between men and women?

"Only a few studies have examined gender differences in risk behaviors for hepatitis C infection," says Marian Butterfield, MD, MPH, lead researcher in the study. "And there've been no studies that examined infection risks among persons with severe mental illness. Understanding gender differences in risk and rate of infection among people with severe mental illness may help us better understand the role of sexual transmission. Though we know a lot about it, there's still some controversy about the risks of sexual transmission."

Drawing from a sample of 251 women and 526 men, the research team found that men had a 19.6 percent rate of hepatitis C infection, twice the 9.8 percent rate among women. "The gender difference in rates of hepatitis C infection persisted across the four study sites," says Dr. Butterfield. "What we were trying to understand is whether gender in and of itself conveys the risk or if it was something having to do with different patterns of risk behavior. We found higher risk behaviors, especially intravenous drug use among men with severe mental illness, while women with severe mental illness had higher rates of sexual risk behaviors."

However, the study found that "gender may modify some of the sexual risks, but the high rates of hepatitis C associated with drug use behaviors appear similar for men and women." It went on to state "the higher rates of hepatitis C among men can be explained primarily by lifetime exposure to injection drug use – specifically needle sharing." Women, the study found, "had significantly more lifetime unprotected sex risks, including vaginal sex, anal sex, sex in exchange for drugs," money or gifts. These sexual risks, however, "do not appear to play a major role in hepatitis C transmission." Only with the risks of hepatitis C infected persons who did not use needles suggest a cumulative role for multiple sexual risk factors, though sex was not the prominent method of hepatitis C infection in this study sample.

Because of the high rate of hepatitis C infection among persons with severe mental illness, part of study's conclusion raises clinical issues for mental health care providers. One is that because "significant gender differences in hepatitis C risk behaviors exist, different assessment and education strategies for men and women that target higher domains of risk may be warranted," especially educating women about sexual risk reduction, vertical transmission, and breastfeeding. It is also important that clinicians assess the risk of injection drug use among men with severe mental illness, as well assess alcohol dependence, common among men with severe mental illness, which can be a factor in the progression of hepatitis C-related liver disease. Finally, men and women with severe mental illness may also be taking multiple medications which are hepatically metabolized and therefore liver function and progression of liver disease would need to be evaluated.

Racial Variations in Osteoarthritis Health Care Utilization

There is no known cure for osteoarthritis (OA). Those who suffer from it, however, have an array of pharmacological treatments, self-care practices, and surgical procedures that can give relief from pain and reduce functional impairment. However, there are documented racial disparities in some areas of OA-related medical care and medication utilization. Understanding these racial variations is important, for these differences may have important implications for quality of care, symptom reduction, and disability.

"There's not a lot of information available as to the reasons for health care disparities for arthritis," says Kelli Dominick, Ph.D., the lead investigator for the study on racial differences in health care utilization among patients with osteoarthritis, published in the October issue of *Journal of Rheumatology**. "But because it is such a common health problem it's important to take a look at what and why there are differences."

For her research, Dr. Dominick and her research colleagues from Durham's HSR&D, Tara Dudley, M.Stat., Steven Grambow, Ph.D., Eugene Oddone, M.D., and Hayden Bosworth, Ph.D., drew on 1,612 white and 861 African American patients who were receiving medical care for OA at the Durham VA Medical Center. Unlike other studies, the white and African American patients examined did not differ in the annual number of physician visits or visits to rheumatologists. Because the VA is an equal-access health care facility with minimal or no co-payments, "financial constraints should have had minimal influence on patients' frequency of physician visitation, medication utilization, or referrals to specialists."

"While we found no significant racial variations in physician services," states Dr. Dominick, "there were some differences in patterns of prescription medication use." About 86% of both white and African American patients were prescribed some analgesic or anti-inflammatory medication. However, there were some racial differences in the use of specific drugs and drug classes. African Americans were prescribed nonselective non-steroidal anti-inflammatory drugs (NSAIDs) 69% and whites 60% of the time; for COX-2 inhibitors, African Americans 4% and whites 7% of the time; and for narcotic analgesics, African Americans 33% and whites 40% of the time.

The study states "these differences may have implications for both quality of pain relief and risk for side effects." Narcotic analgesics "are particularly useful when pain is refractory to treatment with other medications," and non-selective NSAIDs may be associated with an increased risk for gastrointestinal side effects, compared to the newer Cox-2 inhibitors.

The specific reasons for these racial variations in medication use are unknown. "The reasons for racial disparity in medication use can be varied and complicated," says Dr. Dominick. "In the case of use of COX-2 inhibitors, these

require sub-specialist approval. Physicians may be more likely to subscribe these if patients specifically request them. Therefore, differences in a patient's knowledge and request for this medication may explain some of the racial differences in their use." Variations in the use of narcotic analgesics may be due to differences in patient-physician communication about pain or the physician's perception about patient risks for addiction, though this risk has been shown to be minimal in patients with arthritis.

African American patients were also found to have a significantly lower mean days' supply of analgesic and anti-inflammatory drugs during the follow-up year. "This may be because African Americans were prescribed fewer days of medication than whites, or possibly obtained refills less regularly, or discontinued their medication earlier," says Dr. Dominick. "Some patients may also have alternative health care resources and utilize VA services primarily for obtaining prescription medications at low cost, and thus are given longer medication supplies than patients who use VA services more frequently."

Part of the study's conclusion was the need for further examination of racial differences in medication utilization for OA in health care settings where access to care issues are more pronounced.

*Dominick KL, Dudley TK, Grambow SC, Oddone EZ, Bosworth HB. "Racial Differences in Health Care Utilization among Patients with Osteoarthritis" *Journal of Rheumatology* 2003 (October); 30(10):2201-2206.

New Research Associate Fellow Arrives

The Center would like to welcome a new research associate, Dr. Tantina B. Hong, as part of its commitment to supporting healthcare professionals develop applied skills in health services research methods.

Tantina B. Hong, Ph.D., began her Research Supplement for Underrepresented Minorities Fellowship in September. Her research interests are on the underlying individual and dyadic social processes responsible for health behavior and health behavior change. "I'm interested in building a program of research that better incorporates the family and significant social partners in primary, secondary, and tertiary prevention initiatives, and rehabilitation," says Dr. Hong. "It is also critical that research acknowledges that in some family dynamics there may be powerful incentives to facilitate but also undermine conventional treatment. I want to understand the full scope of human environments so that clinical interventions can flourish."

Dr. Hong graduated from Wayne State University, summa

cum laude, with a B.A. in Psychology in 1996. She also completed an M.A. and Ph.D. in Social Psychology, both from Wayne State, in 2000 and 2001, respectively. Her dissertation was *Spouse Involvement in Cardiac Patients' Behavior Change*.

After completing her Ph.D., Dr. Hong had a two-year National Institute of Mental Health post-doctoral fellowship at the Gerontology Center at The Pennsylvania State University. "During this time I became involved in research in criteria for mild cognitive impairment, the health care costs of caregivers, and examined the discrepancies between objective and subjective indicators of health, including the mental health outcomes of such discrepancies," states Dr. Hong. "Specifically, in one study I found that, in spite of the shared poor health objective of those classified as poor health pessimists and optimist groups, the optimists had significantly better outcomes on both depression and functional performance, while the pessimists had more frequent reports of hospitalization, formal help, medical aids, and rehabilitation and convalescent center utilization. This suggests that subjective evaluations of health status, despite objective health indicators, may have important implications for health utilization and costs."

Dr. Hong is the first author of one and coauthor of two journal articles, is the author of numerous paper and poster presentations, and had considerable teaching experience during graduate school. She is also a member of the Gerontology Society of America, the American Psychological Association, and the Society for the Psychological Study of Social Issues.

Faculty Publications

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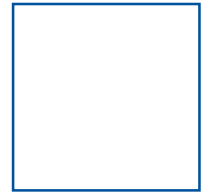
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Research Update



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Faculty Publications (Cont.)

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Research Update is published by the Health Services Research and Development Service, Department of Veterans Affairs Medical Center, Durham. For questions or comments contact Ed Cockrell, Administrative Officer, VAMC (152), 508 Fulton Street, Durham NC, 27705. Telephone: (919) 286-6936, Fax: (919) 416-5836. E-mail: COCKR001@mc.duke.edu Web Page: <http://hsrd.durham.med.va.gov/> The Institute's mission is to provide quality information on issues regarding the organization, financing, and delivery of veterans' health care, and to build the epidemiological capacity of the Veterans Health Administration through the generation, synthesis, and dissemination of epidemiological information. The Institute also has a mission to educate health professionals through a spectrum of training grants in the techniques of health services and epidemiological research.